



MAR 30 2001

1044 '01 APR 13 P3:21

Ms. Berrilyn J. Branch  
Senior Research Scientist  
NatureSmart, Inc.  
12777 Claude Street  
Thornton, Colorado 80241

Dear Ms. Branch:

This is in response to your letter of March 14, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that NatureSmart, Inc. is making the following claims, among others, for the product Nasal-Aid:

- "...support a healthy inflammatory response, soothe sensitive eyes, and promote a healthy allergic response"
- "...provide respiratory support during pollen season"
- "...support a healthy allergic response"
- "...keep your sinuses clear"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, cure, or mitigate a disease, namely seasonal allergies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely,

*for Robert J. Moore*  
for John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

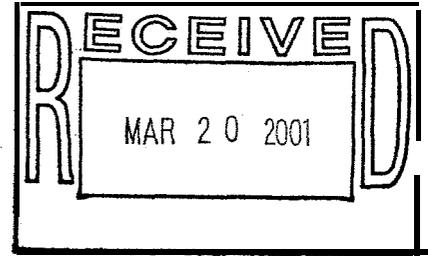
HEALTHSMART  
VITAMINS

www.HSVitamins.com

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THORNTON, CO 80241

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March 14, 2001

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204

NOTIFICATION OF STATEMENTS  
OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to § 403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. § 343 (r)(6).

Name of dietary supplement: Nasal-Aid

Statement(s) of nutritional support:

Formulated with four herbs that nutritionally support a healthy inflammatory response, soothe sensitive eyes, and promote a healthy allergic response.

Eyebright and stinging nettles have been used traditionally to provide respiratory support during pollen season. Quercetin is a potent flavonoid that helps to support a healthy allergic response.

Grape seed extract is a powerful antioxidant.

Help keep your sinuses clear.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement(s) is (are) truthful and not misleading. Two copies of this notification are enclosed with this original.

A handwritten signature in cursive script that reads "Berrilyn J. Branch".

Berrilyn J. Branch,  
Senior Research Scientist  
NatureSmart, Inc.



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